

EPA Registration Jacket

70051-46 Vol. 1

Receipt for Section 3

S: 761958

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Miscellaneous Receipt

Fee For Service: ☐ Yes ☒ No

Company: 70051 CERTIS USA, LLC

V

Print Letter

Enter More Information

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92

Product #: 70051-46

Product Name: SPOD-X LC

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 02-Jun-2004

ic

OPP Rec'd Date: 02-Jun-2004

ic

Front End Date: 02-Jun-2004

ic

Risk Manager Send Date: 10-Jun-2004

ic

Receipt Content

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

final printed labels.

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

RC 37

4/30/07

AIO
JUN 17 2004

sdh
2

NON FEE ITEM

DIVISION: Biopesticides and Pollution Prevention

BRANCH: MPB

EPA FILE SYMBOL/REG. NO: 70051-46

PIN PUNCH/START DATE: 6-3-04

BPPD DATE: 6-9-04

PR 86-5 PASS DATE: N/A

ACTION CODE: 332

RAL: ~~Nancy~~ Nancy Tyler

REMARKS: FINAL Printed Labels

Decision Information for 70051-46

Decision Seq: 339518 Action Code: 150,Gold Seal Letter,0

FFS Start Date: Due Date: OPP Target Due Dt: Registrant Response Due Date: Current Status: CLOSED (29-Mar-2004)

FFS Original Decision: FFS ELP Decision: FFS Sect3 Decision: Start/Stop Clock FQPA Clock: Days Elapsed:

Decision Status

Tracking

Create Resubmission

FFS Delay Letters

FFS Letters

Meetings & Milestones

FFS Information

Decision Ownership

Receipts

Data Package

Reduced Risk

Receipts	Staff Member	Reg/DCI Number	Admin Due Dt	Response
S:754796	Tyler, Nancy	70051-46	13-Feb-2004	GENERAL RESPONSE TO APPLICATION

NA

Viewing Record 1 of 1

MAR 29 2004 RC 38

BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen

REGISTRANT/COMPANY NAME:

Fast Track: Yes ☐ No ☐

Reviewer Tyler

Assigned by PH

EPA REG./FILE SYMBOL 70051-46

[Note: If Fast Track, you may
need to change Reviewer's
Name in PRAT.]

ACTION CODE 350

(New A.I./EUP'S/Tolerances: Yes ☐ No ☐)

Gold Seal

DATE OF APPLICATION 8-7-02

EPA RECEIVED DATE 8-9-02

BPPD RECEIVED DATE 8-22-02

SUBMISSION BARCODE 5620738

ASSIGNED IN PRAT: Yes ☐ No ☐

COMPLETED BY Tyler DATE _____

LOGGED IN BRATS: Yes ☒ No ☐ DATE 9/11 COMPLETED BY PH

RAL RECEIVED _____ DATE _____

(RAL initials)

FINAL ACTION

RESPONSE CODE: 38

RESPONSE DATE: 9/11/02

MOS: _____ (1) Cite All
_____ (4) Not Applicable
_____ (8) Selective

CRP Yes ☐ No ☐
Restricted Use: Yes ☐ No ☐
Manufacturing Use: Yes ☐ No ☐
Exclusive Use: Yes ☐ No ☐

BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen

REGISTRANT/COMPANY NAME:

Certis USA LLC

Fast Track: Yes ☐ No ☒

Reviewer AD Tyler

Assigned by POH

EPA REG./FILE SYMBOL 70051-44

ACTION CODE 350

[Note: If Fast Track, you may
need to change Reviewer's
Name in PRAT.]

(New A.I./EUP'S/Tolerances: Yes ☐ No ☒)

DATE OF APPLICATION 1-14-02

EPA RECEIVED DATE 1-14-02

PM RECEIVED DATE 1-14-02

SUBMISSION BARCODE 5608813

ASSIGNED IN PRAT: Yes ☒ No ☐

COMPLETED BY AD Tyler DATE 1-16-02

LOGGED IN BRATS: Yes ☒ No ☐ DATE 1-23-01

Gold Seal

FINAL ACTION

RESPONSE CODE: 38

RESPONSE DATE: 1-23-01

MOS: _____ (1) Cite All
 _____ (4) Not Applicable
 _____ (8) Selective

CRP Yes ☐ No ☐

Restricted Use: Yes ☐ No ☐

Manufacturing Use: Yes ☐ No ☐

Exclusive Use: Yes ☐ No ☐

REGISTRATION CHRONOLOGY:

[illegible]



Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046

(301) 604-7340

FAX (301) 604-7015
www.certisusa.com

June 2, 2004

Mr. Dennis Szuhay
Branch Chief, Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs
US Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

**Re: Final printed labeling for Certis USA, L.L.C.,
EPA Co. No. 70051**

Dear Mr. Szuhay:

Certis USA, L.L.C. is respectfully submitting the enclosed final printed labeling that incorporates minor changes (Notifications) into the labeling for the following products:

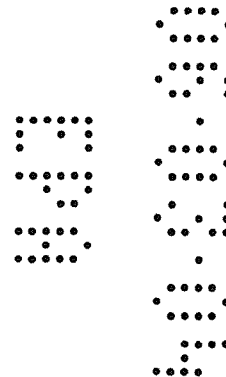
- 1) Spod-X LC, EPA Reg. No. 70051-46
- 2) Agree, EPA Reg. No. 70051-47
- 3) CLV LC, EPA Reg. No. 70051-41
- 4) Thuricide HPWP, EPA Reg. No. 70051-53
- 5) San 420 I Technical Concentrate, EPA Reg. No. 70051-70
- 6) Lepinox XL WDG, EPA Reg. No. 70051-92
- 7) Lepinox XL OF, EPA Reg. No. 70051-94
- 8) Javelin WG 2, EPA Reg. No. 70051-98
- 9) Agree 50 WP, EPA Reg. No. 70051-99

Enclosed in support of this action are: form 8570-1 and 3 copies of each final printed label with changes incorporated. No other changes have been made to these labels. Thank you for your assistance in this matter. Please do not hesitate to contact me if you have any questions about this submission. I can be reached by telephone at 301-483-3806 or by email at cdively@certisusa.com.

Sincerely,

Christine A. Dively
Director of Regulatory Affairs

Enclosures





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70051-46	2. EPA Product Manager Dennis Szuhay	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Spod-X LC	PM# Microbial Pesticides Branch	
5. Name and Address of Applicant (Include ZIP Code) Certis USA, L.L.C. 9145 Guilford Road, Suite 175 Columbia, MD 21046 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification to revise the phrase "Spod-X LC is an IVP (Insecticidal Virus Product)..." on page 1, to read "Spod-X LC is an Insecticidal Virus...". Added the word (heading) "Warranty" over the warranty statement. Revised "Oz. per acre" in the application rates table to read "Fl. Oz. per acre". Three copies of final printed labeling are also included in this submission. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Plastic	
		If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 quart		5. Location of Label Directions <input checked="" type="checkbox"/> on container	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Christine A. Dively		Title Director of Regulatory Affairs		Telephone No. (Include Area Code) 301-483-3806	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature Christine A. Dively		3. Title Director of Regulatory Affairs			
4. Typed Name Christine A. Dively		5. Date May 28, 2004			

Spod-X[®] LC

INSECTICIDAL VIRUS

A Liquid Concentrate Biological Insecticide For Control of Beet Armyworm

FOR ORGANIC PRODUCTION



Active Ingredient:*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of *Spodoptera exigua*

Other Ingredients:

Total:

*This lot contains at least 2 billion OBs/ml.

NOTIFICATION

Date Reviewed: 6-30-04

Reviewed By: [Signature]

NET CONTENTS 1 QUART

EPA Reg. No. 70051-46

EPA Est. No. 70051-CA-001

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Manufactured by
Certis USA, L.L.C.
9145 Guilford Road
Suite 175
Columbia, MD 21046

CERTIS

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

SPOD-X LC is an Insecticidal Virus for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS):

CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Harmful if inhaled. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924.

PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering Control Statements:

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.

USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS: For Terrestrial Uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exemptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates. Thorough spray coverage is essential for good insect control. Apply SPOD-X LC by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Use the application amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application. Use of a spreader/sticker and ultraviolet screening agent can enhance the performance of this product. Fill the mix tank with desired quantity of water. Use agitation during mixing. If spreader/sticker or ultraviolet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Mix final formulation for 10-30 minutes.

APPLICATION RATES

CROP	RATE		
	Billions Obs Per Acre	Mls Per Acre	Fl. Oz Per Acre
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	100 – 200	50 – 100	1.7 – 3.4
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	100 – 200	50 – 100	1.7 – 3.4

CROP	RATE		
	Billions Obs Per Acre	Mls Per Acre	Fl. Oz Per Acre
FLORICULTURE: Chrysanthemum, gysophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	100 – 200	50 – 100	1.7 – 3.4

MAKE APPLICATION WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

This product is for use on both field and greenhouse crops and ornamentals. USE NONCHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC can be applied up to and including the day of harvest and storage. Shake well before using.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

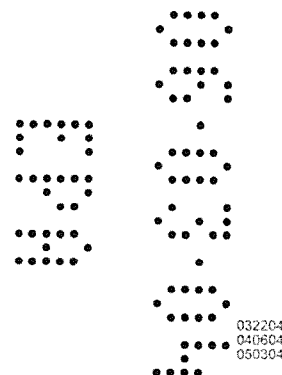
STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90°F. Bioactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.



032204
040604
050304

Spod-X[®] LC

INSECTICIDAL VIRUS

A Liquid Concentrate Biological Insecticide For Control of Beet Armyworm

FOR ORGANIC PRODUCTION



Active Ingredient:*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <i>Spodoptera exigua</i>	0.64%
Other Ingredients:	99.36%
Total:	100.00%

*This lot contains at least 2 billion OBs/ml.

NET CONTENTS 1 QUART
EPA Reg. No. 70051-46
EPA Est. No. 70051-CA-001

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Manufactured by
Certis USA, L.L.C.
9145 Guilford Road
Suite 175
Columbia, MD 21046

CERTIS

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

SPOD-X LC is an Insecticidal Virus for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully.

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If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924.

PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering Control Statements:

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.

USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

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- Coveralls
- Waterproof gloves
- Shoes plus socks

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APPLICATION RATES

CROP	RATE		
	Billions Obs Per Acre	Mls Per Acre	Fl. Oz Per Acre
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	100 – 200	50 – 100	1.7 – 3.4
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	100 – 200	50 – 100	1.7 – 3.4

CROP	RATE		
	Billions Obs Per Acre	Mls Per Acre	Fl. Oz Per Acre
FLORICULTURE: Chrysanthemum, gypsophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	100 – 200	50 – 100	1.7 – 3.4

MAKE APPLICATION WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

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STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

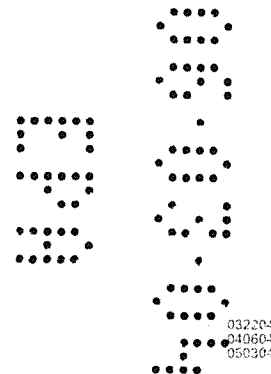
STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90°F. Bioactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Christine A. Dively
Certis USA
9145 Guilford Road, Suite 175
Columbia, MD 21046

DEC 22 2003

Dear Ms. Dively:

Subject: Labeling Amendment
Spod-X LC
EPA Reg. No. 70051-46
Your submission dated 10 September, 2003

The labeling amendment referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, has been received and reviewed and the labeling is acceptable. Please note that your organic language to the label is acceptable. Please submit three (3) copies of your final printed labeling incorporating the changes prior to releasing your product for shipment. A stamped copy is enclosed for your records.

Should you have any questions regarding this correspondence, you may contact Leonard Cole directly at 703.305.5412. We hope that you find this information helpful.

Sincerely,

Dennis Szuhay, Branch Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511C)

Enclosure

CONCURRENCES

SYMBOL	7511C	7511C						
SURNAME	Cole	Szuhay						
DATE	12/22/03	12-22-03						

Spod-X[®] LC

INSECTICIDAL VIRUS

A Liquid Concentrate Biological Insecticide
For Control of Beet Armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully.

 **FOR ORGANIC PRODUCTION**

OMRI
Listed
Organic Materials Review Institute

Active Ingredient:*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of *Spodoptera exigua*

Inert Ingredients:

Total:

0.64%

99.36%

100.00%

*This lot contains at least 2 billion OBs/ml.

CAUTION
KEEP OUT OF REACH OF CHILDREN

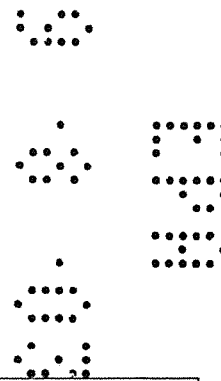
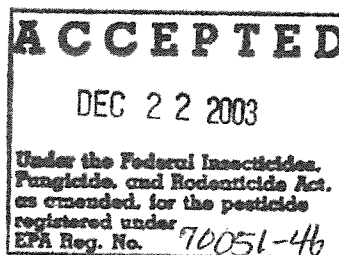
NET CONTENTS 1 QUART

EPA Reg. No. 70051-46

EPA Est. No. 70051-CA-001

Manufactured by
Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046

CERTIS



USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90°F. Bioactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or rinsate that cannot be used should be disposed of on

site or in an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Hot Line Number: 1-800-255-3924.

PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exemptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. Apply SPOD-X LC by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Use the

application amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

Use of a spreader/sticker and ultraviolet screening agent can enhance the performance of this product.

Fill the mix tank with desired quantity of water. Use agitation during mixing. If spreader/sticker or ultraviolet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Mix final formulation for 10-30 minutes.

APPLICATION RATES

CROP	RATE		
	Billions Obs Per Acre	Mls Per Acre	Oz Per Acre
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	100 – 200	50 – 100	1.7 – 3.4
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	100 – 200	50 – 100	1.7 – 3.4
FLORICULTURE: Chrysanthemum, gysophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	100 – 200	50 – 100	1.7 – 3.4

MAKE APPLICATION WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

This product is for use on both field and greenhouse crops and ornamentals. USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC can be applied up to and including the day of harvest and storage. Shake well before using.

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

SHAKE WELL BEFORE USING

SPOD-X[®] LC

A Liquid Concentrate Biological Insecticide For Control of Beet Armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully.

Active Ingredient: Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of *Spodoptera exigua*

Inert Ingredients:

Total:

*This lot contains at least 2 billion OBs/ml.

0.64%
99.36%
100.00%

USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90°F. Bioactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or in an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924.

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS 1 QUART

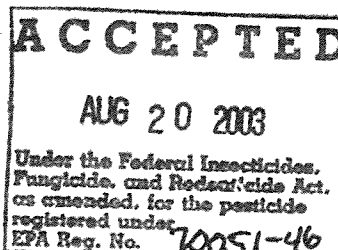
EPA Reg. No. 70051-46

EPA Est. No. 70051-CA-001

PERSONAL PROTECTIVE EQUIPMENT: Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.



MANUFACTURED BY: CERTIS

Certis USA, L.L.C. • 9145 Guilford Road, Suite 175, Columbia, MD 21046

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exemptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

Coveralls • Waterproof gloves • Shoes plus socks.

GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If spreader/sticker or ultraviolet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

RECOMMENDED APPLICATION RATES

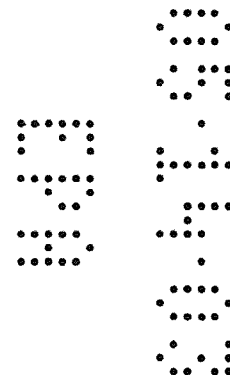
CROP	RATE		
	Billions OBS Per Acre	Mls Per Acre	Oz Per Acre
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	100 - 200	50 - 100	1.7 - 3.4
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	100 - 200	50 - 100	1.7 - 3.4
FLORICULTURE: Chrysanthemum, gysophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	100 - 200	50 - 100	1.7 - 3.4

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

This product is for use on both field and greenhouse crops and ornamentals. USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC may be applied up to and including the day of harvest and storage. Shake well before using.

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

SHAKE WELL BEFORE USING



M_050603V2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

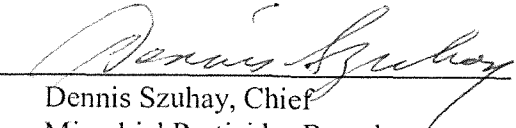
I, Dennis Szuhay, Chief, Microbial Pesticides Branch, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the products may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product. Further, the recipient of this letter is on notice that the status of the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration and/or the product label for the product listed below. EPA has issued a registration number for the product listed below to:

Certis USA
9145 Guilford Road, Suite 175
Columbia, MD 21046

EPA REGISTRATION NUMBER
70051-46

NAME OF PRODUCT
Spod-X LC


Dennis Szuhay, Chief
Microbial Pesticides Branch

3-16-04

[Date]

CONCURRENCES

SYMBOL	7511C	7511C						
SURNAME	Tyler	Szuhay						
DATE	3-15-04	3-16-04						

CERTIS

Certis USA
9145 Guilford Road
Suite 175
Columbia MD 21046
(301) 604-7340
FAX (301) 604-7015
www.certisusa.com

February 11, 2004

Ms. Nancy Tyler
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway, Crystal Mall 2
Arlington, VA 22202

RE: Gold Seal Requests

Dear Ms. Tyler:

Certis USA L.L.C. (EPA Company No. 70051) respectfully requests that EPA provide three Gold Seal Letters for each of the following products:

Product

Agree 50 WP
Cyd-X
Javelin WG2
Spod-X LC
Gemstar LC
Agree WG

EPA Registration No.

70051-99 ✓
70051-44 ✓
70051-98 ✓
70051-46 ✓
70051-45 ✓
70051-47 ✓

154796

We have included three copies of each label to assist in this request. Once the Gold Seal Letters are complete, please forward them to my attention at the following address:

Certis USA L.L.C.
9145 Guilford Rd. Suite 175
Columbia, MD 21046

Please feel free to contact me if you have any questions about this submission. I can be reached by telephone at (301)483-3806 or by email at cdively@certisusa.com.

Sincerely,

Christine A. Dively
Christine A. Dively
Director of Regulatory Affairs

Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

I, Phillip Hutton, Chief, Microbial Pesticides Branch, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the products may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product. Further, the recipient of this letter is on notice that the status of the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration and/or the product label for the product listed below. EPA has issued a registration number for the product listed below to:

Certis USA L.L.C.
9145 Gilford Rd, Suite 175
Columbia, MD 21046

EPA REGISTRATION NUMBER

70051-46

NAME OF PRODUCT

Spod-X LC



Phillip Hutton, Chief
Microbial Pesticides Branch

SEP 16 2002

[Date]

CONCURRENCES

SYMBOL	7511C							
SURNAME	Tyler							
DATE	9-12-02							

CERTIS

Certis USA
9145 Guilford Road
Suite 175 -
Columbia, MD 21046
(301) 604-7340
FAX (301) 604-7015
www.certisusa.com

August 07, 2002

Nancy Tyler
U.S. Environmental Protection Agency
Office of Pesticide Programs (BPPD)
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

RE: Certis USA Gold Seal Request

Dear Ms. Tyler:

Certis USA L.L.C. (EPA Company No. 70051) respectfully requests EPA to provide three Gold Seal Letters for each of the following 9 products:

9 Products

EPA Registration No.

Neemix	70051-5
Neemix 4.5	70051-9
Spod-X LC ✓	70051-46
Gemstar LC ✓	70051-45
Agree WG ✓	✓70051-47
Teknar HP-D	✓70051-51
Thuricide 48LV	✓70051-57
Javelin WG	✓70051-66
Thuricide Technical Concentrate	70051-68

Please find enclosed copies of the most recent EPA approved labels (3 copies for each product). Once the Gold Seal Letters are complete, please forward them to my attention at the following address:

Certis USA L.L.C.
9145 Guilford Rd. Suite 175
Columbia, MD 21046

SPOD-X® LCA Liquid Concentrate Biological Insecticide
For Control of Beet Armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully.

Active Ingredient:	Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <i>Spodoptera exigua</i>	0.64%
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Inert Ingredients:		99.36%
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*This lot contains at least 2 billion OBs/ml

ESTABLISHMENT No. 67250-IL-1

EPA REGISTRATION No. 58788-7

CAUTION**KEEP OUT OF THE REACH OF CHILDREN****PRECAUTIONARY STATEMENTS:****HAZARDS TO HUMANS (AND DOMESTIC ANIMALS):** Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.**PERSONAL PROTECTIVE EQUIPMENT:** Applicators and other handlers must wear:

Long-sleeved shirt and long pants • Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

STATEMENT OF PRACTICAL TREATMENT: In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.**USER SAFETY RECOMMENDATION**

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters.**STORAGE AND DISPOSAL:** Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.**STORAGE:** Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90°F. Bioactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life.**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.**CONTAINER DISPOSAL:** Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will kill workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and instructions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas that are restricted under the Worker Protection Standard (WPS) of 4 hours. PPE required for entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls • Waterproof gloves • Shoes plus socks

GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the larvae and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good larval control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, soil, equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application or in 10-15 gallons of water for aerial application.

A spreader/flicker and ultra-fine mist screening agent may enhance the performance of this product. Fill the mix tank with desired quantity of water. Application should be used during mixing. If a spreader/flicker or ultra-fine mist screen is used, add prior the addition of SPOD-X LC. Mixing time can be reduced by pre-mixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

RECOMMENDED APPLICATION RATES

CROP	RATE		
	Millions OBs Per Acre	lbs Per Acre	oz Per Acre
Veg (tablets): Tomatoes, lettuce, cabbage, beans, peppers, celery, asparagus, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	100 - 200	50 - 100	1.7 - 3.4
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarcane	100 - 200	50 - 100	1.7 - 3.4
Floriculture: Chrysanthemum, gerbera, carnation, azalea, gladiolus, cyclamen, marigold, geranium, Bougainvillea	100 - 200	50 - 100	1.7 - 3.4

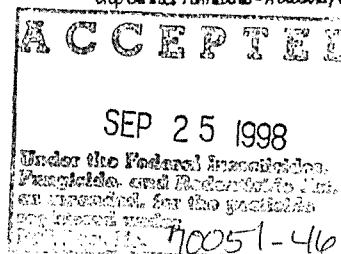
APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBs TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

This product is for use on both field and greenhouse crops and ornamentals. USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC may be applied up to and including the day of harvest and storage. Shake well before using.

LIMITED WARRANTY

Crop Genetics International makes no warranty, express or implied, including the warranties of merchantability and fitness for any particular purpose concerning this product except those which are contained on this label.

Crop Genetics International - A Subsidiary of Ingersoll • 10150 Old Columbia Road • Columbia, MD 21046



United States Environmental Protection Agency

I, Phillip Hutton, Chief, Microbial Pesticides Branch, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the products may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product. Further, the recipient of this letter is on notice that the status of the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration and/or the product label for the product listed below. EPA has issued a registration number for the product listed below to:

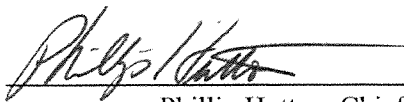
Certis USA L.L.C.
9145 Guilford Road, Suite 175
Columbia, MD 21046

EPA REGISTRATION NUMBER

70051-46

NAME OF PRODUCT

Spod-X LC

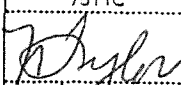


Phillip Hutton, Chief
Microbial Pesticides Branch

JAN 23 2002

[Date]

CONCURRENCES

SYMBOL ▶	7511C							
SURNAME ▶								
DATE ▶	1-16-02							



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

I, Phillip Hutton, Chief, Microbial Pesticides Branch, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the products may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

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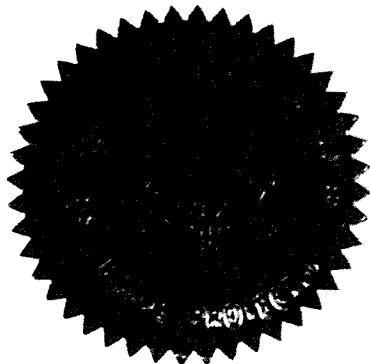
Certis USA L.L.C.
9145 Guilford Road, Suite 175
Columbia, MD 21046

EPA REGISTRATION NUMBER

70051-46

NAME OF PRODUCT

Spod-X LC



Phillip Hutton, Chief
Microbial Pesticides Branch

JAN 23 2002

[Date]

SPOD-X® LC

A Liquid Concentrate Biological Insecticide
For Control of Beet Armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully.

Active Ingredient:	Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <i>Spodoptera estigae</i>	0.64%
Inert Ingredients:		99.36%

*This lot contains at least 2 billion OBs/ml

ESTABLISHMENT No. 67250-IL-1
EPA REGISTRATION No. 59788-7

KEEP OUT OF THE REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

PERSONAL PROTECTIVE EQUIPMENT: Applicators and other handlers must wear:
Long-sleeved shirt and long pants • Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

STATEMENT OF PRACTICAL TREATMENT: In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.

USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90°F. Bioactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only trained handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.
PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Chemical • Waterproof gloves • Shoes plus socks

GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions: Insure that larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.
Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultraviolet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

RECOMMENDED APPLICATION RATES

CROP	RATE		
	Billion OBs Per Acre	MG Per Acre	Oz Per Acre
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, asparagus, beets, cauliflower, cucumber, broccoli, onion	100 - 200	50 - 100	1.7 - 3.4
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	100 - 200	50 - 100	1.7 - 3.4
Floriculture: Cyclamen, geranium, petunia, rose, carnation, azalea, gladiolus, cyclamen, zinnia, geranium, Begonia	100 - 200	50 - 100	1.7 - 3.4

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBs TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

This product is for use on both field and greenhouse crops and ornamentals. USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC may be applied up to and including the day of harvest and storage. Shake well before using.

LIMITED WARRANTY

Crop Genetics International makes no warranty, express or implied, including the warranty of merchantability and fitness for any particular purpose, concerning the subject except those which are contained on this label.

Crop Genetics International - A Subsidiary of Albion • 10150 Old Columbia Road • Columbia, MD 21046

ACCEPTED

for shipment and use of product for experimental purposes under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act.

Permit No.

Issued on

ACCEPTED
SEP 25 1998
Under the Federal Insecticide, Fungicide, and Rodenticide Act, no exemption for the pesticide was granted under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act.
70051-46

PRODUCT INFORMATION - APPLICATION

Recommended Application Rates

CROP	RATE		
	Billions OBs Per Acre	Mls Per Acre	
Vegetables: matatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control
Other Crops: alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweet potatoes, tobacco, sunflower, sugarbeets	200	100	
Ornamentals: nysanthemum, gysophila, gerbera, rose, carnation, azalea, cyclamen, santipaulia, geranium, Bouvardia	200	100	

is product is for use on both field and greenhouse crops and ornamentals. USE NON CHLORINATED WATER AT A pH NEAR 7.0. THE SPRAY-TANK MIX. SPOD-X LC may be applied up to and including the day of harvest and storage.

LIMITED WARRANTY

Crop Genetics International makes no warranty, express or implied, including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

TECHNICAL BULLETIN - SPOD-X LC BIOLOGICAL INSECTICIDE

PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labeled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

SPOD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of *Spodoptera exigua*.

Active Ingredient:	Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <i>Spodoptera exigua</i>	0.64%
Inert Ingredients:		99.36%

*This lot contains at least 2 billion OBs/ml.

BIOLOGICAL PROPERTIES

SPOD-X LC belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. The virions consist of rod-shaped nucleocapsids that are surrounded by an envelope. The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

MODE OF ACTION

The virus must be ingested to be infective. When ingested, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible. Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter. Within a day after ingestion, the usually clear molymph becomes increasingly cloudy. Another 1-2 days later, polyhedral-shaped bodies are detected in the blood. Depending on dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, the body becomes flaccid and the integument ruptures, releasing billions of OBs.

***APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBs TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.**

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LC does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.

SPOD-X LC

A Liquid Concentrate Biological Insecticide
for Control of Beet Armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient:	Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <i>Spodoptera exigua</i>	0.64%
Inert Ingredients:		99.36%

*This lot contains at least 2 billion OBs/ml.

**KEEP OUT OF THE REACH OF CHILDREN
CAUTION
STATEMENT OF PRACTICAL TREATMENT**

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.

ESTABLISHMENT No. S8788-MD-002

EPA REGISTRATION No. 58766-7

Net Volume:

Lot No.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

PRECAUTIONARY STATEMENTS: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

PERSONAL PROTECTIVE EQUIPMENT: Applicators and other handlers must wear:

Long-sleeved shirt and long pants • Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F. Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or residue that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container - Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

Glass container - Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.
(Refer to Technical Bulletin for Additional Guidelines for Use.)

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls • Waterproof gloves • Shoes plus socks

GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

SHAKE WELL BEFORE USING

Crop Genetics International • 10150 Old Columbia Road • Columbia, MD 21046

PRODUCT INFORMATION - APPLICATION

Recommended Application Rates

CROP	RATE		
	Billion OBs Per Acre	Mls Per Acre	
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweet potatoes, tobacco, sunflower, sugarbeets	200	100	
Floriculture: Chrysanthemum, gypsophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	200	100	

This product is for use on both field and greenhouse crops and ornamentals. USE NON-CHLORINATED WATER at a pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC may be applied up to and including the day of harvest and storage.

LIMITED WARRANTY

Crop Genetics International makes no warranty, express or implied, including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

TECHNICAL BULLETIN - SPOD-X LC BIOLOGICAL INSECTICIDE

PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labeled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

SPOD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of *Spodoptera exigua*.

Active Ingredient*	Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <i>Spodoptera exigua</i>	0.64%
Inert Ingredients:		99.36%

*This lot contains at least 2 billion OBs/ml.

BIOLOGICAL PROPERTIES

SPOD-X LC belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are surrounded by an envelope. The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

MODE OF ACTION

The virus must be ingested to be infective. When ingested, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible. Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter. Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedral-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBs TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LC does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.

SPOD-X[®] LC

A Liquid Concentrate Biological Insecticide
for Control of Beet Armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient*	Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <i>Spodoptera exigua</i>	0.64%
Inert Ingredients:		99.36%

*This lot contains at least 2 billion OBs/ml

KEEP OUT OF THE REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.
ESTABLISHMENT No. 58788-MD-002
EPA REGISTRATION No. 58788-7
Net Volume: 10150 Old Columbia Road
Columbia, MD 21046
Lot No.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

PRECAUTIONARY STATEMENTS: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

PERSONAL PROTECTIVE EQUIPMENT: Applicators and other handlers must wear:

Long-sleeved shirt and long pants • Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F. Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke. Glass container - triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.
(Refer to Technical Bulletin for Additional Guidelines for Use.)

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls • Waterproof gloves • Shoes plus socks

GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

SHAKE WELL BEFORE USING

Crop Genetics International • 10150 Old Columbia Road • Columbia, MD 21046

PRODUCT INFORMATION - APPLICATION

Recommended Application Rates

CROP	RATE		
	Billions OBs Per Acre	Mls Per Acre	
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	200	100	
Floriculture: Chrysanthemum, gypsophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	200	100	

This product is for use on both field and greenhouse crops and ornamentals. USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC may be applied up to and including the day of harvest and storage.

LIMITED WARRANTY

Crop Genetics International makes no warranty, express or implied, including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

TECHNICAL BULLETIN - SPOD-X LC BIOLOGICAL INSECTICIDE

PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

SPOD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of *Spodoptera exigua*.

Active Ingredient*	Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <i>Spodoptera exigua</i>	0.64%
Inert Ingredients:		99.36%

*This lot contains at least 2 billion OBs/ml.

BIOLOGICAL PROPERTIES

SPOD-X LC belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are surrounded by an envelope. The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

MODE OF ACTION

The virus must be ingested to be infective. When ingested, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible. Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter. Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedral-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBs TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LC does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.

SPOD-X[®] LC

A Liquid Concentrate Biological Insecticide
for Control of Beet Armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient*	Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <i>Spodoptera exigua</i>	0.64%
Inert Ingredients:		99.36%

*This lot contains at least 2 billion OBs/ml

**KEEP OUT OF THE REACH OF CHILDREN
CAUTION
STATEMENT OF PRACTICAL TREATMENT**

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.

ESTABLISHMENT No. 58788-MD-002

EPA REGISTRATION No. 58788-7

Net Volume:

Lot No.

Mfg. By:

Crop Genetics International

10150 Old Columbia Road

Columbia, MD 21046

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

PRECAUTIONARY STATEMENTS: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

PERSONAL PROTECTIVE EQUIPMENT: Applicators and other handlers must wear:

Long-sleeved shirt and long pants • Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F. Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

Glass container - triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

(Refer to Technical Bulletin for Additional Guidelines for Use.)

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls • Waterproof gloves • Shoes plus socks

GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

SHAKE WELL BEFORE USING

Crop Genetics International • 10150 Old Columbia Road • Columbia, MD 21046

PRODUCT INFORMATION - APPLICATION

Recommended Application Rates

CROP	RATE		
	Billions OBs Per Acre	Mis Per Acre	
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	200	100	
Floriculture: Chrysanthemum, gypsophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	200	100	

This product is for use on both field and greenhouse crops and ornamentals. USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC may be applied up to and including the day of harvest and storage.

LIMITED WARRANTY

Crop Genetics International makes no warranty, express or implied, including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

TECHNICAL BULLETIN - SPOD-X LC BIOLOGICAL INSECTICIDE

PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

SPOD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of *Spodoptera exigua*.

Active Ingredient*	Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <i>Spodoptera exigua</i>	0.64%
Inert Ingredients:		99.36%

*This lot contains at least 2 billion OBs/ml

BIOLOGICAL PROPERTIES

SPOD-X LC belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded in a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are surrounded by an envelope. The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

MODE OF ACTION

The virus must be ingested to be infective. When ingested, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible. Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter. Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBs TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LC does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.

SPOD-X[®] LC

A Liquid Concentrate Biological Insecticide
for Control of Beet Armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient*	Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <i>Spodoptera exigua</i>	0.64%
Inert Ingredients:		99.36%

*This lot contains at least 2 billion OBs/ml

**KEEP OUT OF THE REACH OF CHILDREN
CAUTION
STATEMENT OF PRACTICAL TREATMENT**

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.

ESTABLISHMENT No. 58768-MD-062

EPA REGISTRATION No. 58768-7

Net Volume

Lot No.

Mfg. By

Crop Genetics International

10150 Old Columbia Road

Columbia, MD 21046

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

PRECAUTIONARY STATEMENTS: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

PERSONAL PROTECTIVE EQUIPMENT: Applicators and other handlers must wear:

Long sleeved shirt and long pants • Shoes plus socks

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place, inaccessible to children and pets. Store at temperatures below 90° F. Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide spray mixture or residue that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke. Glass container - triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

(Refer to Technical Bulletin for Additional Guidelines for Use.)

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls • Waterproof gloves • Shoes plus socks

GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

SHAKE WELL BEFORE USING

Crop Genetics International • 10150 Old Columbia Road • Columbia, MD 21046

PRODUCT INFORMATION - APPLICATION

Recommended Application Rates

CROP	RATE		
	Billions OBs Per Acre	Mis Per Acre	
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweet potatoes, tobacco, sunflower, sugarbeets	200	100	
Floriculture: Chrysanthemum, gypsophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, santipaula, geranium, Bouvardia	200	100	

This product is for use on both field and greenhouse crops and ornamentals. USE NON-CHLORINATED WATER at a pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC may be applied up to and including the day of harvest and storage.

LIMITED WARRANTY

Crop Genetics International makes no warranty, express or implied, including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

TECHNICAL BULLETIN - SPOD-X LC BIOLOGICAL INSECTICIDE

PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

SPOD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of *Spodoptera exigua*.

Active Ingredient*	Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <i>Spodoptera exigua</i>	0.64%
Inert Ingredients:		99.36%

*This lot contains at least 2 billion OBs/ml.

BIOLOGICAL PROPERTIES

SPOD-X LC belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are surrounded by an envelope. The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

MODE OF ACTION

The virus must be ingested to be infective. When ingested, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible. Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter. Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBs TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LC does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.

SPOD-X LC

A Liquid Concentrate Biological Insecticide
for Control of Beet Armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient*	Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <i>Spodoptera exigua</i>	0.64%
Inert Ingredients:		99.36%

*This lot contains at least 2 billion OBs/ml.

KEEP OUT OF THE REACH OF CHILDREN CAUTION STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.

ESTABLISHMENT No. 58768-MD-002

EPA REGISTRATION No. 58768-7

Net Volume:

Lot No.

Mfg. By:

Crop Genetics International

10150 Old Columbia Road

Columbia, MD 21046

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

PRECAUTIONARY STATEMENTS: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

PERSONAL PROTECTIVE EQUIPMENT: Applicators and other handlers must wear:

Long-sleeved shirt and long pants • Shoes plus socks

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F. Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or residue that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container - Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke. Glass container - Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. (Refer to Technical Bulletin for Additional Guidelines for Use.)

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls • Waterproof gloves • Shoes plus socks

GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

SHAKE WELL BEFORE USING

Crop Genetics International • 10150 Old Columbia Road • Columbia, MD 21046



FACSIMILE MESSAGE

TO: Linda Hollis

DATE: September 3, 1998

COMPANY: U.S. Environmental Protection Agency

FAX NO.: (703) 308-7026

TOTAL PAGES: 15
(including cover)

FROM: Jim Messina

MESSAGE: As instructed in your voice mail message dated September 3, 1998, please find attached a copy of the June 25, 1996 submission package, a copy of the June 26, 1996 EPA receipt form, a copy of your August 14, 1996 approval letter, and a copy of the August 27, 1996 final submission. Please note that the label and correspondence reflects Biosys, Inc. and Crop Genetics International; however, Thermo Trilogy Corporation now owns these companies and the product registrations have been officially transferred to us. The current registration number for Gemstar LC is 70051-46.

I look forward to receiving an EPA stamped approved copy of the enclosed label. If you need any additional information, please contact me at (301) 483-3812. Thank you for your help in this matter.

9145 Guilford Rd.
Suite 175
Columbia, MD 21046

The information contained in this facsimile message is intended only for the use of the individuals to whom it is addressed and may contain information that is privileged and confidential. If the reader of this message is not the intended recipient, you are hereby notified that any use, dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately at (301) 483-3812. Thank you.



August 27, 1996

Linda Hollis
Biopesticides and Pollution Prevention Division (7501W)
Office of Pesticide Programs
Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

**Subject: Continuation of Application for Label Amendments Dated June 25,
1996 - Submission of Corrected Labels per EPA Request Dated
Aug 14, 1996**

SPOD-X® LC, EPA Reg. No. 58788-7

Dear Ms. Hollis:

In response to your letter dated August 14, 1996, I am submitting herein five (5) copies of the SPOD-X® labeling with the requested change. I am also enclosing a copy of your August 14 letter, and an EPA Form 8570-1 (Application for Pesticide - Other).

We appreciate your timely response to our application for these minor label amendments, and look forward to receiving a stamped copy of the label for our files.

If there are any further questions, please contact me at (410) 381-3819. Thank you again for your continued assistance.

Sincerely

David P. Miller
Manager of Regulatory Affairs

A BIOLOGICAL PEST CONTROL COMPANY

10150 OLD COLUMBIA ROAD, COLUMBIA, MD 21046-1704 • (410) 381-3800 • FAX (410) 381-3840

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 05-31-98



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

246011

Application for Pesticide - Section I

1. Company/Product Number EPA Reg. No. 58788-7	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sped-X [®] LC	PM# 90	
5. Name and Address of Applicant (Include ZIP Code) Crop Genetics International/biosys 10150 Old Columbia Road Columbia, MD 21046 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of 5 copies of corrected labeling per EPA request in Letter dated August 14, 1996

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper, glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name David P. Miller		Title Manager of Regulatory Affairs	Telephone No. (Include Area Code) 410-381-3819
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
Signature 		3. Title Manager of Regulatory Affairs	
4. Typed Name David P. Miller		5. Date August 27, 1996	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 14 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

David P. Miller
Manager, Regulatory Affairs
Crop Genetics International/BioSys
10150 Old Columbia Road
Columbia, Maryland 21046-1274

Dear Mr. Miller:

Subject: SPOD-X LC
EPA Reg. No. 58788-7
Application for label amendments dated 6/25/96

The labeling amendments referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended, is acceptable with the following comment.

1. Place the "Keep Out of Reach of Children" statement before the signal word "Caution".

Submit five (5) copies of the labeling with this change. Any further questions, contact Linda Hollis @ (703) 308-8733.

Sincerely,

A handwritten signature in cursive script, appearing to read "Linda Hollis".

Linda Hollis
Regulatory Action Leader
Biopesticides and Pollution Prevention Division
7501W



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

06/26/96

DAVID P. MILLER
CROP GENETICS INTERNATIONAL
10150 OLD COLUMBIA RD
COLUMBIA MD 210461704

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

PRODUCT NAME: SPOD-X LC
COMPANY NAME: CROP GENETICS INTERNATIONAL
OPP IDENTIFICATION NUMBER: 245606
EPA REGISTRATION NUMBER: 58788-7
EPA RECEIPT DATE: 06/26/96

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Phil Hutton, Product Manager 90, at (703)-308-8260.

Sincerely,

J. Wrice

Front End Processing Staff
Information Services Branch
Program Management and Support Division

biosys

RECD EPA/OPP/DPD2

'96 JUN 26 A8:53

June 25, 1996

Phil Hutton (PM-18)
Office of Pesticide Programs
Document Processing Desk (AMEND)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

**Subject: Minor label amendment, SPOD-X® LC Biological Insecticide, EPA
Number 58788-7**

Dear Mr. Hutton:

biosys is making several minor changes to the labeling on the above-referenced product. Attached are: (1) form 8570-1 describing the changes, (2) a copy of the previously approved, EPA-stamped label for this product, and (3) five copies of the new label copied onto 8½×11 paper. I have highlighted the changes on the first copy of the label.

As outlined on the form 8570-1, the changes in this label are:

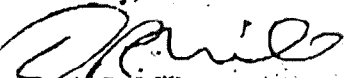
- The restricted entry interval in the WPS section was reduced from 12 hours to 4, as was discussed at a Crop Genetics International (CGI) / EPA meeting held April 13, 1995, and attended by you, Janet Anderson, Bill Schneider, and Roy Sjoblad. *ok*
- The application rate table was modified to allow a range of use rates from the prior label rate down to half that rate. *ok*
- The section of the product label which had been referred to as the "technical bulletin" was deleted. This portion of the label had no required statements. *ok*

No new crops or insects were added, and no changes were made to required label statements other than those described above. *✓*

As you are aware, CGI was acquired by biosys early in 1995. We will soon submit the require documentation to effect a full transfer of all of CGI's registrations and supporting data to biosys.

If you should have any questions regarding this amendment, please contact me at (410) 381-3819, or via fax at (410) 381-3844.

Sincerely,



David P. Miller
Manager of Regulatory Affairs

A BIOLOGICAL PEST CONTROL COMPANY

10150 OLD COLUMBIA ROAD, COLUMBIA, MD 21046-1704 • (410) 381-3800 • FAX (410) 381-3340



June 25, 1996

Phil Hutton (PM-18)
Office of Pesticide Programs
Document Processing Desk (AMEND)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

**Subject: Minor label amendment, SPOD-X® LC Biological Insecticide, EPA
Number 58788-7**

Dear Mr. Hutton:

biosys is making several minor changes to the labeling on the above-referenced product. Attached are: (1) form 8570-1 describing the changes, (2) a copy of the previously approved, EPA-stamped label for this product, and (3) five copies of the new label copied onto 8½×11 paper. I have highlighted the changes on the first copy of the label.

As outlined on the form 8570-1, the changes in this label are:

- The restricted entry interval in the WPS section was reduced from 12 hours to 4, as was discussed at a Crop Genetics International (CGI) / EPA meeting held April 13, 1995, and attended by you, Janet Anderson, Bill Schneider, and Roy Sjoblad.
- The application rate table was modified to allow a range of use rates from the prior label rate down to half that rate.
- The section of the product label which had been referred to as the "technical bulletin" was deleted. This portion of the label had no required statements.

No new crops or insects were added, and no changes were made to required label statements other than those described above.

As you are aware, CGI was acquired by biosys early in 1995. We will soon submit the require documentation to effect a full transfer of all of CGI's registrations and supporting data to biosys.

If you should have any questions regarding this amendment, please contact me at (410) 381-3819, or via fax at (410) 381-3844.

Sincerely,

David P. Miller
Manager of Regulatory Affairs

A BIOLOGICAL PEST CONTROL COMPANY

10150 OLD COLUMBIA ROAD, COLUMBIA, MD 21046-1704 • (410) 381-3800 • FAX (410) 381-3840

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 05-31-98



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number
245469

Application for Pesticide - Section I

1. Company/Product Number 58788-7	2. EPA Product Manager Phil Hutton	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SPOD-X LC	PM# 18	
5. Name and Address of Applicant (Include ZIP Code) Crop Genetics International-A Subsidiary of biosys 10150 Old Columbia Rd. Columbia MD 21046-1274 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Minor label amendment:

1. REI Changed from 12 hours to 4 hours.
2. Modified the application rate.
3. Deleted non-required label elements.

Section - III

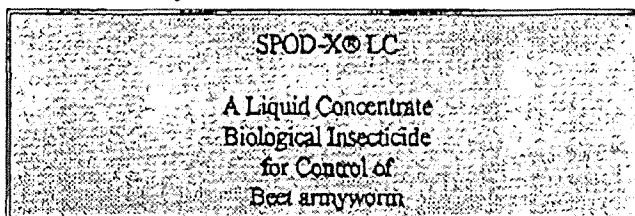
1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
Certification must be submitted If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name David P. Miller	Title Manager of Regulatory Affairs	Telephone No. (Include Area Code) 410-381-3800
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		8. Date Application Received (Stamped)
nature	3. Title Manager of Regulatory Affairs	
4. Typed Name David P. Miller	5. Date 6-25-96	

SPOD-X LC DRAFT LABELLING

Page 1 of 6



SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of Spodoptera exigua

0.64%

Inert Ingredients:

99.36%

*This lot contains at least 2 billion OBs/ml.

KEEP OUT OF THE REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.

Mfg. By: Crop Genetics International
10150 Old Columbia Road
Columbia, MD 21046

ESTABLISHMENT No. 58788-MD-002

EPA REGISTRATION No.

Net Volume:

Lot No.

ACCEPTED
with COMMENTS
in EPA Letter Dated

MAR 02 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

58788-7

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

Precautionary Statements: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

Personal Protective Equipment: Applicators and other handlers must wear
Long-sleeved shirt and long pants
Shoes plus socks

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F.

Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL:

Plastic container—triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

Glass container—triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

(Refer to Technical Bulletin for Additional Guidelines for Use.)

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

PRODUCT INFORMATION

Application

Recommended Application Rates

CROP	RATE		
	Billion OBs Per Acre	Mls Per Acre	
Vegetables Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control.
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	200	100	
Floriculture Chrysanthemum, gypsophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	200	100	

This product is for use on both field and greenhouse crops and ornamentals.

USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX

SPOD-X LC may be applied up to and including the day of harvest and storage.

Limited Warranty: Crop Genetics International, makes no warranty, express or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

TECHNICAL BULLETIN SPOD-X LC BIOLOGICAL INSECTICIDE

PRODUCT DESCRIPTION

produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus) designed to control caterpillars of labelled insect pests.

provides a unique opportunity for biological control of insect caterpillars without harmful effects on domestic animals, wildlife, beneficial insects and plants.

is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of Spodoptera

●
lient*
edraal occlusion bodies (OBs) of the
ar polyhedrosis virus of Spodoptera exigua

0.64%

ents: 99.36

lot contains at least 2 billion OBs per ml.

BIOLOGICAL PROPERTIES

belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are included within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The ● within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are covered by an envelope.

is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be stored at 0° F.

MODE OF ACTION

must be ingested to be infective. When infected, at early stages of larval development, infection results in death. The OBs dissolve within seconds in the midgut after ingestion. The released virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the midgut and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells of tissues are susceptible.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 12, 1997

Mr. Jow-Li Su, President
Thermo Triology Corporation
7500 Grace Drive
Columbia, MD 21044

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dear Mr. Su:

Subject: Transfer of Pesticide Registrations and Data From
Company Number 58788 to Company Number 70051

Pursuant to your request in your letter and transfer agreement undated (received February 10, 1997), we have approved the transfer of the following registrations and data from **Crop Genetics International Corporation**, company number 58788, to **Thermo Triology Corporation**, company number 70051.

The effective date of these changes is the date of this letter.

<u>Registered Products</u>	<u>Old EPA Reg. No.</u>	<u>New EPA Reg. No.</u>
SPOD-X Wettable Powder	58788-1	70051-42
Gusano Biological Pesticide	58788-3	70051-43
CYD-X	58788-4	70051-44
GEMSTAR LC	58788-5	70051-45
SPOD-X LC	58788-7	70051-46

You also requested transfer of the Experimental Use Permit, 58788-EUP-1, "INCIDE". According to our records this EUP is inactive and has expired and therefore is not eligible for transfer.

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the

effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

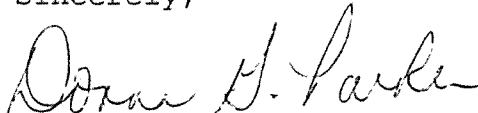
Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer undated (received February 10, 1997) to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date **Thermo Triology Corporation** will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460-0001

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,



Donna G. Parker
Information Management Specialist
Information Services Branch
Information Resources & Services Div (7504C)

cc: Dr. Edwin C. Quattlebaum, President & CEO
Crop Genetics International Corporation
10150 Old Columbia Road
Columbia, MD 21046



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

238312

Application for Pesticide - Section I

1. Company/Product Number 58788-7	2. EPA Product Manager Phil Hutton	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SPOD-X^R LC	PM# 18	
5. Name and Address of Applicant (Include ZIP Code) Crop Genetics International 10150 Old Columbia Road Columbia, Maryland 21046 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below. Resubmission: in response to Agency letter dated _____	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated March 2, 1995 <input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name R. Mark Beach		Title Director, Product Development	
		Telephone No. (Include Area Code) 410-381-3800	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			
2. Signature <i>R. Mark Beach</i>		3. Title Director, Product Development	
4. Typed Name R. Mark Beach		5. Date April 28, 1995	
6. Date Application Received (Stamped) 5/31/95 BPPD			

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (TS-767)
WASHINGTON, DC 20460

EPA REGISTRATION NO.

58788-7

DATE OF ISSUANCE

MAR 02 1995

TERM OF ISSUANCE

NOTICE OF PESTICIDE:

☒ REGISTRATION
☐ REREISTRATION

(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

NAME OF PESTICIDE PRODUCT

SPOD-X^R LC

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

CROP GENETICS INTERNATIONAL
10150 Old Columbia Road
Columbia, Maryland 21046

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is ~~conditionally~~ registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you: ²⁻¹⁻⁹⁵ BPPD

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA sec. 4.

2. Make the following label changes:

Revise the EPA Registration Number to read "58788-7"

☐ ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

Robert L. Anderson

DATE

3/2/95

SPOD-X LC DRAFT LABELLING

Page 1 of 6

SPOD-X® LC

A Liquid Concentrate
Biological Insecticide
for Control of
Beet armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient*

Polyhedral occlusion bodies (OBs) of the
nuclear polyhedrosis virus of Spodoptera
exigua

0.64%

Inert Ingredients:

99.36%

*This lot contains at least 2 billion OBs/ml.

KEEP OUT OF THE REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.

Mfg. By: Crop Genetics International
10150 Old Columbia Road
Columbia, MD 21046

ACCEPTED
with COMMENTS
in EPA Letter Dated

ESTABLISHMENT No. 58788-MD-002

MAR 02 1995

EPA REGISTRATION No.

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
is recorded, for the pesticide
registered under EPA Reg. No.

Net Volume:

58788-7

Lot No.

SPOD-X LC DRAFT LABELLING

Page 2 of 6

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

Precautionary Statements: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

Personal Protective Equipment: Applicators and other handlers must wear
Long-sleeved shirt and long pants
Shoes plus socks

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F.

Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL:

Plastic container—triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

Glass container—triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

SPOD-X LC DRAFT LABELLING

Page 3 of 6

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

(Refer to Technical Bulletin for Additional Guidelines for Use.)

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

SPOD-X LC DRAFT LABELLING

Page 4 of 6

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

PRODUCT INFORMATION

Application

Recommended Application Rates

CROP	RATE		
	Billion OBs Per Acre	Mls Per Acre	
Vegetables Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control.
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	200	100	
Floriculture Chrysanthemum, gypsophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	200	100	

This product is for use on both field and greenhouse crops and ornamentals.

USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX

SPOD-X LC may be applied up to and including the day of harvest and storage.

Limited Warranty: Crop Genetics International, makes no warranty, express or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

SPOD-X LC DRAFT LABELLING

Page 5 of 6

TECHNICAL BULLETIN SPOD-X LC BIOLOGICAL INSECTICIDE

PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

SPOD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of Spodoptera exigua.

Active Ingredient*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Spodoptera exigua</u>	0.64%
--	-------

Inert Ingredients:	99.36
--------------------	-------

*This lot contains at least 2 billion OBs per ml.

BIOLOGICAL PROPERTIES

SPOD-X LC belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are surrounded by an envelope.

The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

MODE OF ACTION

The virus must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible.

SPOD-X LC DRAFT LABELLING

Page 6 of 6

Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

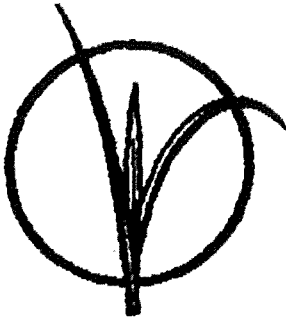
Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LC does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.

Crop Genetics International
10150 Old Columbia Road
Columbia, MD 21046



CROP GENETICS INTERNATIONAL

10150 OLD COLUMBIA ROAD

COLUMBIA, MD 21046-1704

PHONE: (410)381-3800 FAX: (410)381-3840

ATTENTION:

Linda Hollis

COMPANY:

EPA

FAX NUMBER:

703-308-7026

FROM:

Mark Beach

DATE:

2/27/95

TOTAL PAGES:

358788-T

MESSAGE:

The MRID # is 43537501
as per attached

FEB 10 1995

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

CROP GENETICS INTERNATIONAL
10150 OLD COLUMBIA ROAD
COLUMBIA, MD 21046

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 02/07/95. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

435375-00

TRANSMITTAL DOCUMENTNAME AND ADDRESS OF SUBMITTER

Crop Genetics Int'l
10150 Old Columbia Rd
Columbia, MD 21046

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Application to amend pending registration

DATE RECEIVED BY EPA

2/7/95

LIST OF SUBMITTED STUDIES:

Supplement to Spod-X LC Product Chemistry;
58788-T; Guidelno 151A-15

Ac 37501

FOR ISB USE

Date to ISB:	Company No.:	Reg. No.(s):
Date to Index:	Guideline:	
Date frm Indx:	Page Count:	
Addressee:	Groundwater? State(s):	
Notify:	Chem. Name(s) & Code(s):	
Category: 1) 6a2	2) adv. flag	



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☒ Other

OPP Identifier Number

238310

Application for Pesticide - Section I

1. Company/Product Number 58788-T	2. EPA Product Manager Phil Hutton	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Spod-X LC	PM# 18	
5. Name and Address of Applicant (Include ZIP Code) Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Revised CSF and Five batch analysis per EPA letter dated 2/3/95

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name James H. Davis		Title Vice President	
		Telephone No. (Include Area Code) (410) 381-3800	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Vice President	
4. Typed Name James H. Davis		5. Date 02/06/95	

435375-01

Title

Supplement to
Spod-X® LC - Product Chemistry

Volume Number

II of II

Data Requirement

Pesticide Assessment Guidelines
Subdivision M, Guideline #151A-15

EPA's File Symbol

58788-T

Author

R. Mark Beach

Completed On:

February 6, 1995

Performing Laboratory

Crop Genetics International
10150 Old Columbia Road
Columbia, MD 21046
(410) 381-3800

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA §10 (d) (1) (A), (B), or (C) has been removed to a confidential appendix and is cited by cross-reference number in the body of the study.

Company: Crop Genetics International

Company Agent: James H. Davis

Title: Vice President

James H. Davis
Signature

2/6/95
Date

GOOD LABORATORY PRACTICE STATEMENT

EPA's Good Laboratory Practice Standards (40 CFR 160; Fed. Reg. 34052, August 17, 1989) do not apply to Pesticide Assessment Guideline Number 151A-15.

Place Holder Page

This place holder page is inserted in place of all pages found in the confidential attachment.

Cross Reference 1
151A-15 Certification of Ingredient Limits

Pages 66-68 - *Access to FIFRA health and safety data is restricted under FIFRA section 10(g)*

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 03 1995

170 / 5471605
Hollis

James H. Davis
Vice President of Research
and Development
Crop Genetics International
10150 Old Columbia Road
Columbia, MD. 21046

Subject: Spod-X LC
EPA File Symbol 58788-T

Dear Mr. Davis:

The submission referred to above, submitted in connection with registration under FIFRA as amended will be acceptable when you submit the following:

1. Submit a revised CSF and a five batch analysis expressing the total number of occlusion bodies in the preparation.

Sincerely,

Janet L. Andersen, Acting Director
Biopesticides and Pollution Prevention
Division

CONCURRENCES							
SYMBOL	7501W	7501W					
SURNAME	Hollis	J. Chow					
DATE	2/2/95	3 Feb 95					



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

238309

Application for Pesticide - Section I

1. Company/Product Number 58788-T	2. EPA Product Manager Phil Hutton	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Spod-X [®] LC	PM# 18	
5. Name and Address of Applicant (Include ZIP Code) Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Forms 8570-20 and 8570-29 submitted herewith per request.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
Name James H. Davis		Title Vice President		
		Telephone No. (Include Area Code) (410) 381-3800		
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) 	
2. Signature 		3. Title Vice President		
4. Typed Name James H. Davis		5. Date 1/10/95		

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States
Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0060
Approval Expires 02-28-95

Certification with Respect to Citation of Data

Applicants Name and Address

Crop Genetics Intenational
10150 Old Columbia Rd,
Columbia, MD 21046

EPA File Symbol/Registration Number 58788-T

Product Name Spod-X[®] LC

Date of Application July 21, 1994

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study.

I am the original submitter*; or

I have obtained the written permission of the original submitter for _____, which is
(insert name of chemical)
(for multiple chemicals link the companies who are original data submitters
(insert names of companies)
with the appropriate chemical name) to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study;

a. I am the original data submitter*; or

I have obtained the written permission of the original data submitter for _____, which is
(insert name of chemical)
(for multiple chemicals link the companies who are original data submitters
(insert names of companies)
with the appropriate chemical name) to cite that study*; or

b. I have notified in writing the companies _____ for _____ that
(insert names of companies) (insert name of chemical)
have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

Companies _____ for _____ (for multiple
(insert names of companies) (insert name of chemical)
chemicals link the companies who are original data submitters with the appropriate chemical name)
listed on the Pesticide Data Submitters List for all active ingredients contained in my product
(cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer
Statement below.)

Companies _____ for _____ (for multiple
(insert names of companies) (insert name of chemical)
chemicals link the companies who are original data submitters with the appropriate chemical name)
that have submitted the studies which I have cited (Selective method*).

4. ☒ I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature *James H. Davis*

Name and Title James H. Davis, Vice President

Date January 6, 1995

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

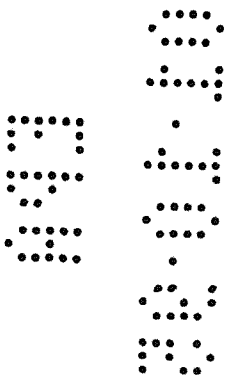
Signature

Name and Title

Date

Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 2.5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining needed data, and completing and reviewing this application form. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M Street, S. W., Washington, DC 20460; and to Office of Management and Budget, Paperwork Reduction Project (2070-0055), Washington, DC 20503, marked "Attention Desk Officer for EPA."





U.S. ENVIRONMENTAL PROTECTION AGENCY
REGISTRATION DIVISION (TS-767)
WASHINGTON, D.C. 20460

DATA REFERENCE SHEET

(See instructions on the back of the last page before completing.)

1. PAGE

1 OF 2

2. EPA REGISTRATION NO./FILE SYMBOL 58788-T

3. APPLICANT'S NAME AND ADDRESS

Crop Genetics International
10150 Old Columbia Rd.
Columbia, MD 21046

4. PRODUCT NAME

Spod-X^R LC

5. PRODUCT MANAGER

Phil Hutton, PM 18

6. TO ACCOMPANY APPLICATION FOR REGISTRATION DATED:

July 21, 1994

7. NAME OF STUDY	SOURCE OF STUDY				f. ACCESSION NUMBER (if known)
	a. APPLICANT CONDUCTED STUDY (mark 'X')	b. OBTAINED FROM EPA (mark 'X')	c. OBTAINED FROM ANOTHER FIRM OR SOURCE (give name and address)	d. OBTAINED FROM PUBLIC LITERATURE (give reference)	
151A10-17 Product Chemistry	X				
152A-10 Acute Oral Toxicity/Pathogenicity				Referenced in Data Waiver Request	
152A-11 Acute Dermal Toxicity				Referenced in Data Waiver Request	
152A-12 Acute Pulmonary Toxicity/Pathogenicity				Referenced in Data Waiver Request	
Intraperitoneal Injection Toxicity/Pathogenicity	X				
152A-14 Primary Eye Irritation				Referenced in Data Waiver Request	
152A-15 Hypersensitivity Incidents				Referenced in Data Waiver Request	
152A-16 Cell Culture	X				
Tier II, Tier III Toxicity Studies				Referenced in Data Waiver Request	
154A-16 Avian Oral Toxicity				Referenced in Data Waiver Request	

If you marked "X" in this column, do you wish your name placed on the Data Submitters List?

☐ YES
☒ NO

BURDEN STATEMENT FOR DATA REFERENCE SHEET
(EPA Form 8570-20; OMB Form No. 0070-0060)

The public reporting burden for this collection of information is estimated to average one hour per completed Data Reference Sheet. This includes reviewing instructions, identifying pertinent references, and citing the references on this instrument. It is estimated that approximately eight (8) hours are required to prepare a complete set of references for an initial application to register a "typical" or "average" chemical. After that, additional supporting references may be necessary but would not require the number of references necessary for an initial application to register. Send comments regarding this burden, to: Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0060), Washington, DC 20503

01-10-82

EBH



U.S. ENVIRONMENTAL PROTECTION AGENCY
REGISTRATION DIVISION (TS-767)
WASHINGTON, D.C. 20460

DATA REFERENCE SHEET

(See instructions on the back of the last page before completing.)

1. PAGE

2 OF 2

2. EPA REGISTRATION NO./FILE SYMBOL

58788-T

3. APPLICANT'S NAME AND ADDRESS

Crop Genetics International
10150 Old Columbia Rd.,
Columbia, MD 21046

4. PRODUCT NAME

Spod-X[®] LC

5. PRODUCT MANAGER

Phil Hutton, PM 18

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July 21, 1994

SOURCE OF STUDY

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154A-14 Freshwater Fish Test				Referenced in Data Waiver Request		
154A-20 Freshwater Aquatic Invertebrate Test				Referenced in Data Waiver Request		
154A-21 Estuarine and Marine Animal Tests				Referenced in Data Waiver Request		
154A-22 Nontarget Plant Studies				Referenced in Data Waiver Request		
154A-23 Nontarget Insect Studies				Referenced in Data Waiver Request		
154A-24 Honeybee Tests				Referenced in Data Waiver Request		

If you marked "X" in this column, do you wish your name placed on the Data Submitters List?

☐ YES
☐ NO

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(EPA Form 8570-20; OMB Form No. 0070-0060)

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07-10-88

ENV



CROP GENETICS INTERNATIONAL

10150 OLD COLUMBIA ROAD
COLUMBIA MD 21046-1704 USA
TEL 410 381 3800
FAX 410 381 3840

October 31, 1994

BY HAND

Janet Andersen
Director, Biological Pollution Prevention Division
Office of Pesticide Programs
U. S. Environmental Protection Agency
Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia

RE: Pending Spod-X[®] LC Registration - No. 58788-T

Dear Ms. Andersen:

At the meeting you held last month with representatives of the Biotechnology Industry Organization ("BIO"), you indicated your interest in insuring not only that biological products were registered, but also that they were actually used in the agricultural community. We share your interest and are actively developing a range of insecticidal virus products for sale in the United States and overseas.

One product that we have focused on extensively is the Spod-X insecticidal virus for control of the beet armyworm on cotton, vegetables and greenhouse crops. A wettable powder formulation of this product is already registered with EPA. Since registering this product, we have developed a liquid formulation that has enhanced shelf-life stability and greater grower acceptance. This liquid formulation is currently being sold in the Netherlands in the greenhouse market where it has gained rapid market acceptance due to its high efficacy.

CGI desires to begin selling this liquid formulation in the United States next summer for control of beet armyworm on cotton and vegetables. As you may know, current products being sold do not adequately control this pest, and last summer several Section 18 emergency exemption requests were filed for the use of unregistered chemical products. We believe that we have a product that will meet the farmers' needs and we have the production capacity to supply the product.

What we lack is an approved label for the liquid formulation. In July of this year, we submitted an application for the new formulation - No. 58788-T. The only difference between the liquid formulation and the already approved formulation is the addition of an

Janet Andersen, Director

October 31, 1994

Page 2

inert that is listed on EPA's recently published list of Minimal Risk Inerts. Thus there are not any toxicology or environmental issues associated with the new formulation.

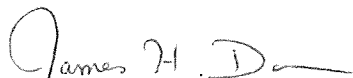
For CGI to be in a position to market this product next summer, it is essential that CGI obtain approval for this formulation as soon as possible. This is the first product we will market in the United States. We need to have sufficient time to print final labels, to package product and distribute it to dealers, to obtain and publish advertising, and to complete the myriad of tasks necessary for successful market entrance. While these tasks may be routine for large chemical companies, they are not for us. Many of these tasks can not be completed until we have a final label.

CGI would appreciate any help that you can provide in expediting this registration. Ideally, these types of formulation changes involving inerts of no toxicological significance should be approved in a matter of weeks not months. I know this is one of your goals for the new division. Unfortunately, if CGI is to be able to supply cotton farmers with adequate beet armyworm control next summer, we can not wait for the new division to be up and running at full speed.

I will call you next week to discuss with you CGI's pending registration. If a meeting would be appropriate, I would be happy to meet with you at any time. In the meantime if you need any additional information, please call me at 410 -381-3803.

Thank you for your attention to this matter.

Sincerely,



James H. Davis
Vice President of Research
and Development

cc: Stephen L. Johnson
Phillip O. Hutton



CROP GENETICS INTERNATIONAL

10150 OLD COLUMBIA ROAD
COLUMBIA MD 21046-1704 USA
TEL 410 381 3800
FAX 410 381 3840

October 31, 1994

BY HAND

Janet Andersen
Director, Biological Pollution Prevention Division
Office of Pesticide Programs
U. S. Environmental Protection Agency
Crystal Mall 2
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Is there
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OCT 31 1994

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REGISTRATION DIVISION
H-7505C

Janet Andersen, Director

October 31, 1994

Page 2

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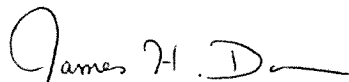
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Sincerely,



James H. Davis
Vice President of Research
and Development

cc: Stephen L. Johnson ✓
Phillip O. Hutton



CROP GENETICS INTERNATIONAL

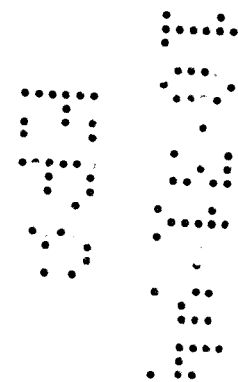
10150 OLD COLUMBIA ROAD
COLUMBIA MD 21046-1704 USA
TEL 410 381 3800
FAX 410 381 3840

October 31, 1994

BY HAND

Janet Andersen
Director, Biological Pollution Prevention Division
Office of Pesticide Programs
U. S. Environmental Protection Agency
Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia

LAH
FYI



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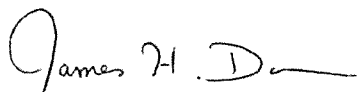
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Thank you for your attention to this matter.

Sincerely,


James H. Davis
Vice President of Research
and Development

cc: Stephen L. Johnson
✓ Phillip O. Hutton ✓

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) 	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number <div style="font-size: 1.5em; font-weight: bold;">186786</div>
	Application for Pesticide:		

Section I

1. Company/Product Number <div style="font-weight: bold;">58788- T</div>	2. EPA Product Manager <div style="font-weight: bold;">Phil Hutton</div>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <div style="font-weight: bold;">Spod - X^B LC</div>	PM# <div style="font-weight: bold;">#18</div>	
5. Name and Address of Applicant (Include ZIP Code) <div style="font-weight: bold;">Crop Genetics International 10150 Old Columbia Road Columbia, Maryland 21046</div> <div style="margin-top: 10px;"> <input type="checkbox"/> Check if this is a new address </div>		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name <u>Spod - X^B LC</u>

Section II

<input type="checkbox"/> Amendment - Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other - explain below.
--	--

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

New Formulation of already registered active ingredient
For greenhouse and field crops and ornamentals

Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Unit Package wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input checked="" type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted.			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container <div style="font-weight: bold;">1.0 gal, 2.0gal, 5.0 gal 0.01gal, 0.13gal, 0.5gal</div>	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other (_____) <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name <div style="font-weight: bold;">James H. Davis</div>	Title <div style="font-weight: bold;">Vice President</div>	Telephone No. (Include Area Code) <div style="font-weight: bold;">410-381-3800</div>
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		
2. Signature 	3. Title <div style="font-weight: bold;">Vice President</div>	6. Date Application Received (Stamped) <div style="text-align: center;"> </div>
4. Typed Name <div style="font-weight: bold;">James H. Davis</div>	5. Date <div style="font-weight: bold;">July 21, 1994</div>	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your **Company Number**, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the **Product Number**.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

Confidential Statement of Formula may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 25, 1994

CROP GENETICS INTERNATIONAL
ATTN: JAMES H. DAVIS
10150 OLD COLUMBIA RD
COLUMBIA, MD 21046

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: SPOD X^RLC
COMPANY NAME: CROP GENETICS INTERNATIONAL
OPP IDENTIFICATION NUMBER: 186786
EPA FILE SYMBOL: 58788-T
EPA RECEIPT DATE: 07/22/94

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for a new registration and it has passed an administrative screen for completeness.

The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions please contact Phil Hutton
Product Manager 18 , at (703)305-7690.

Sincerely,

Front End Processing Staff
Information Services Branch
Program Management and Support Division



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber **87**



CROP GENETICS INTERNATIONAL

10150 OLD COLUMBIA ROAD
COLUMBIA MD 21046-1704 USA
TEL 410 381 3800
FAX 410 381 3840

BY HAND

July 21, 1994

Office of Pesticide Programs
Environmental Protection Agency
Document Processing Desk (APPL)
Room 266A, Crystal Mall #2,
1921 Jefferson Davis Highway
Arlington, VA 22202

Attn: Philip Hutton, PM18

Re: New Product Registration Application for Spod-X® LC
EPA Symbol 58788

Dear Mr. Hutton:

Crop Genetics International respectfully submits the following application for a new formulation of its Spod-X® bioinsecticide for control of beet armyworm. This liquid formulation is targeted, among other things, for the control of beet armyworm in cotton. Subject to regulatory approval, Crop Genetics would expect to sell this product next summer in the United States. A similar formulation (differing only in the concentration of the active ingredient) is already being sold in the Netherlands for control of beet armyworm on greenhouse crops.

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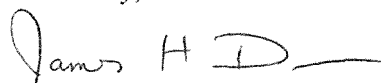
Volume I Administrative Materials
 Application for Pesticide Registration (EPA Form 8570-1)
 Confidential Statement of Formula
 Five copies of a draft Label

Volume II(a) Spod-X® LC Product Chemistry - Guidelines #151A-10 through 151A-15,
 151A-17

(b) Spod-X® LC Product Chemistry - Guideline #151A-16.

Please do not hesitate to contact me if you have any questions about the submitted package or any other issues related to the registration of Spod-X LC.

Sincerely,


James H. Davis
Vice President of Research
& Development



CROP GENETICS INTERNATIONAL

10150 OLD COLUMBIA ROAD
COLUMBIA MD 21046-1704 USA
TEL 410 381 3800
FAX 410 381 3840

BY HAND

July 21, 1994

*file stamp
Copy*

Office of Pesticide Programs
Environmental Protection Agency
Document Processing Desk (APPL)
Room 266A, Crystal Mall #2,
1921 Jefferson Davis Highway
Arlington, VA 22202

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Volume II(a) Spod-X® LC Product Chemistry - Guidelines #151A-10 through 151A-15,
151A-17

(b) Spod-X® LC Product Chemistry - Guideline #151A-16.

Please do not hesitate to contact me if you have any questions about the submittal package or any other issues related to the registration of Spod-X LC.

Sincerely,

James H. Davis
James H. Davis
Vice President of Research
& Development



CROP GENETICS INTERNATIONAL

10150 OLD COLUMBIA ROAD
COLUMBIA MD 21046-1704 USA
TEL 410 381 3800
FAX 410 381 3840

BY HAND

July 21, 1994

Office of Pesticide Programs
Environmental Protection Agency
Document Processing Desk (APPL)
Room 266A, Crystal Mall #2,
1921 Jefferson Davis Highway
Arlington, VA 22202

Attn: Philip Hutton, PM18

Re: New Product Registration Application for Spod-X® LC
EPA Symbol 58788

Dear Mr. Hutton:

Crop Genetics International respectfully submits the following application for a new formulation of its Spod-X® bioinsecticide for control of beet armyworm. This liquid formulation is targeted, among other things, for the control of beet armyworm in cotton. Subject to regulatory approval, Crop Genetics would expect to sell this product next summer in the United States. A similar formulation (differing only in the concentration of the active ingredient) is already being sold in the Netherlands for control of beet armyworm on greenhouse crops.

Accordingly, enclosed are:

Volume I Administrative Materials

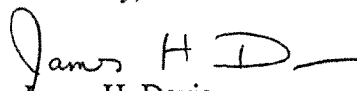
Application for Pesticide Registration (EPA Form 8570-1)
Confidential Statement of Formula
Five copies of a draft Label

Volume II(a) Spod-X® LC Product Chemistry - Guidelines #151A-10 through 151A-15,
151A-17

(b) Spod-X® LC Product Chemistry - Guideline #151A-16.

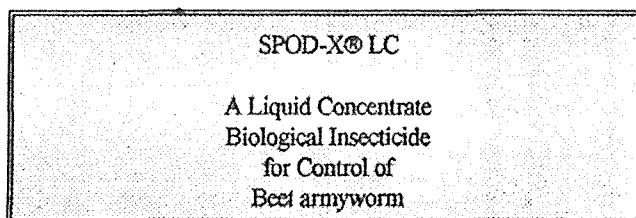
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& Development

SPOD-X LC DRAFT LABELLING

Page 1 of 6



SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient*

Polyhedral occlusion bodies (OBs) of the
nuclear polyhedrosis virus of Spodoptera
exigua

0.64%

Inert Ingredients:

99.36%

*This lot contains at least 2 billion OBs/ml.

KEEP OUT OF THE REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.

Mfg. By: Crop Genetics International
10150 Old Columbia Road
Columbia, MD 21046

ESTABLISHMENT No. 58788-MD-002

EPA REGISTRATION No.

Net Volume:

Lot No.

SPOD-X LC DRAFT LABELLING

Page 2 of 6

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

Precautionary Statements: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

Personal Protective Equipment: Applicators and other handlers must wear
Long-sleeved shirt and long pants
Shoes plus socks

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F.

Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL:

Plastic container—triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

Glass container—triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

SPOD-X LC DRAFT LABELLING

Page 3 of 6

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

(Refer to Technical Bulletin for Additional Guidelines for Use.)

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

SPOD-X LC DRAFT LABELLING

Page 4 of 6

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

PRODUCT INFORMATION

Application

Recommended Application Rates

CROP	RATE		
	Billion OBs Per Acre	Mls Per Acre	
Vegetables Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control.
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	200	100	
Floriculture Chrysanthemum, gypsophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	200	100	

This product is for use on both field and greenhouse crops and ornamentals.

USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX

SPOD-X LC may be applied up to and including the day of harvest and storage.

Limited Warranty: Crop Genetics International, makes no warranty, express or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

SPOD-X LC DRAFT LABELLING

Page 5 of 6

TECHNICAL BULLETIN SPOD-X LC BIOLOGICAL INSECTICIDE

PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

SPOD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of Spodoptera exigua.

Active Ingredient*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Spodoptera exigua</u>	<u>0.64%</u>
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Inert Ingredients:	<u>99.36</u>
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*This lot contains at least 2 billion OBs per ml.

BIOLOGICAL PROPERTIES

SPOD-X LC belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are surrounded by an envelope.

The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

MODE OF ACTION

The virus must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible.

SPOD-X LC DRAFT LABELLING

Page 6 of 6

Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

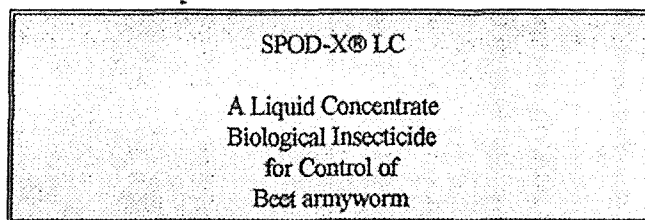
Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LC does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.

Crop Genetics International
10150 Old Columbia Road
Columbia, MD 21046

SPOD-X LC DRAFT LABELLING

Page 1 of 6



SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

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0.64%

Inert Ingredients:

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*This lot contains at least 2 billion OBs/ml.

KEEP OUT OF THE REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.

Mfg. By: Crop Genetics International
10150 Old Columbia Road
Columbia, MD 21046

ESTABLISHMENT No. 58788-MD-002

EPA REGISTRATION No.

Net Volume:

Lot No.

SPOD-X LC DRAFT LABELLING

Page 2 of 6

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

Precautionary Statements: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

Personal Protective Equipment: Applicators and other handlers must wear
Long-sleeved shirt and long pants
Shoes plus socks

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F.

Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

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Plastic container—triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

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DIRECTIONS FOR USE

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(Refer to Technical Bulletin for Additional Guidelines for Use.)

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- Coveralls
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GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

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A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

SPOD-X LC DRAFT LABELLING

Page 4 of 6

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PRODUCT INFORMATION

Application

Recommended Application Rates

CROP	RATE		
	Billion OBs Per Acre	Mls Per Acre	
Vegetables Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control.
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	200	100	
Floriculture Chrysanthemum, gypsophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	200	100	

This product is for use on both field and greenhouse crops and ornamentals.

USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX

SPOD-X LC may be applied up to and including the day of harvest and storage.

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SPOD-X LC DRAFT LABELLING

Page 5 of 6

TECHNICAL BULLETIN SPOD-X LC BIOLOGICAL INSECTICIDE

PRODUCT DESCRIPTION

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SPOD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of Spodoptera exigua.

Active Ingredient*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Spodoptera exigua</u>	<u>0.64%</u>
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Inert Ingredients:	<u>99.36</u>
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*This lot contains at least 2 billion OBs per ml.

BIOLOGICAL PROPERTIES

SPOD-X LC belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are surrounded by an envelope.

The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

MODE OF ACTION

The virus must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible.

SPOD-X LC DRAFT LABELLING

Page 6 of 6

Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

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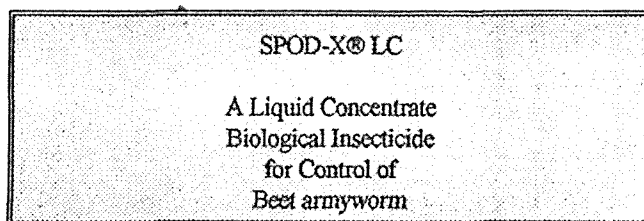
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Crop Genetics International
10150 Old Columbia Road
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SPOD-X LC DRAFT LABELLING

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SPOD-X LC DRAFT LABELLING

Page 4 of 6

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SPOD-X LC DRAFT LABELLING

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The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

MODE OF ACTION

The virus must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible.

SPOD-X LC DRAFT LABELLING

Page 6 of 6

Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LC does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.

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Pages 109-114 - *Confidential Statements of Formula may be entitled to confidential treatment*